GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:33
ANSWERED ON:01.12.2004
SPURIOUS DRUGS
Zahedi Shri Mahboob

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether drugs valued at Rs. 20,000 crores are manufactured in India against import of drugs valued at Rs. 4000 crore;

(b) if so, whether big companies like Sun Pharmaceuticals Industries and Glaxo are reported to have undertaken corrupt practices even in the sale of life saving drugs after expiry date by relabelling and mixing vitamins ;

(c) if so, whether the Government seized a lot of such spurious drugs in Delhi, Gujarat, Bombay and Maharashtra;

(d) whether Letroval/Letrozol, a Sun Pharma drug which is widely used in breast cancer and infertility beyond the norms of UFSD ; and

(e) if so, the steps taken by the government against such corrupt practices?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH & FAMILY WELFARE (SMT. PANBAKA LAKSHMI)

(a): As per the feedback available from Department of Chemicals and Petrochemicals, Ministry of Chemicals and Fertilizers, the Indian Pharmaceutical Industry is now US $ 4 billion industry in addition to over US $ 3.1 billion in exports. So far as import of medicinal and pharmaceuticals products are concerned, Rs.1701.46 crores, Rs.2026.58 crores, Rs.2865.20 crores and Rs.2955.63 crores (Prov.) worth of medicinal and pharmaceutical products have been imported in the country during the period 2000-01, 2001-02, 2002-03 & 2003-04 respectively.

(b)&(c): Under the provisions of Drugs and Cosmetics Act, 1940, and Rules thereunder, the State Governments are empowered to regulate and monitor the quality of drugs moving in the market. Action against any complaints for possible manufacture or sale of spurious drugs including sale of life saving drugs after expiry dates is taken by State Govts. through their respective drugs control organisations. Details of the complaints with the drug control authorities of States/UTs are not maintained centrally. However, Govt. of India has been taking various initiatives to ensure uniform and strict action to tackle the problem of spurious drugs. Some of such specific initiatives are as follows:

(i) The issues concerning alleged sale of spurious drugs was taken up by Union Health minister with State Health Ministers in the conference of Central Council of Health and Family Welfare.

(ii) Meeting of State Drug Controllers together with representatives of Pharma industry and trade organisations was arranged.

(iii) Financial assistance is being provided to States for augmentation of drug testing facilities.

(iv) Matter concerning sale of spurious drugs and initiatives to be taken up by State Governments were taken up by Union Health Minister with all Chief Ministers in October, 2002.

(v) A World Bank assisted Capacity Building Project on Food Safety and Quality Control of Drugs has been launched with effect from October, 2003. This project aims at strengthening, inter-alia, the drug regulatory infrastructure in the country by augmenting the drug testing facilities by providing for equipments, civil works, staff and consumables and extensive training of drug regulatory/quality control officials and industry personnel. Annual drug testing capacity to be raised to 1,00,000 samples as against 36,000 to 38,000 samples.

(vi) Special training programme for improving investigations and legal skills are organised for state officials.

(d)&(e): Letrozole had been approved for M/s Sun Pharmaceuticals as second line treatment of advanced breast cancer in women. Since, no formal approval was issued for its use as a fertility drug, the firm was issued a notice to explain their alleged promotion of Letrozole as a fertility drug. The firm was warned not to engage in any promotional activity, which leads to off-lable use of anti-cancer drug for fertility enhancement. An advisory communication that Letrozole has not been approved as treatment for infertility has also been issued to all the Drug Controllers of States/UTs.